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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,604	02/05/2004	Thomas Roballey	1330.004	7751

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EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,604	ROBALLEY, THOMAS	
	Examiner	Art Unit	
	Bruce E. Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-24* is/are pending in the application.

4a) Of the above claim(s) *5,6,14 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7-11 and 20-24* is/are rejected.

7)☒ Claim(s) *3,4,12,13 and 15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/16/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of the species having a rupture indicator that is a dye causing a body change of a change in color of the urine in the reply filed on 5/16/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 5-6, 14, and 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species.

Response to Arguments

Applicant's arguments filed 5/16/05 have been fully considered. Regarding the Gerow reference, Gerow teaches that biologically compatible rupture indicator can be contained within the elastomeric envelope and capable of leaking out:

"Although the silicone gel contained in the envelope of a silicone based prosthesis could be marked with barium sulfate"; see column 5, lines 6-9.

"Accordingly, it is an object of the present invention to provide a breast prosthesis composed of a **flexible envelope**, such as a silicone elastomer envelope, **and suitable contents** which has been labeled with a radioopaque marker which absorbs electromagnetic energy different from **the envelope and its contents** and different from surrounding breast tissue and in a pattern or configuration which enables roentgenographic determination of whether the envelope is intact, has ruptured, or has an impending fold-fault rupture." See column 5, lines 27 et seq.

It is the Examiner's position that Gerow teaches radiopaque marker can be added within the implant and inherently could leak therefrom.

Applicant has amendment the claims including the limitation "causing a body change detectable to the patient" which is very broad and is not defined in applicant's specification. Gerow teaches adding barium sulfate to an implant and using x-rays to check for a rupture which is similar to applicant's now cancelled claim 19. It is within the scope of this new limitation that barium sulfate could cause a body change detectable to a patient, such as an allergic reaction, change in shape, or illness, to which the patient could detect. Additionally, it is also with the scope that a patient could perform the x-ray procedure on themselves. Any material added into the envelope other than the filling material is capable of leaking out and causing at least a change in shape of the implant which the patient could detect. Note Gerow teaches the filling materials can be a combination of silica gel and saline. The Examiner interprets the saline as the fill and the silica gel as the rupture indicator.

Allowable Subject Matter

Claims 3-4, 12-13 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "biologically compatible rupture indicator" is not support; the specification use the terminology "chemical indicator".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 8 positively claims portions of the body. Suggested language: change "implated" to "implatable".

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bill, III (4,100,627).

Bill, III teaches a prosthesis for implant in a human patient body comprising:

at least one elastomeric envelope [and] a filling material contained in the elastomeric envelope; and

a biologically compatible rupture indicator (pigment/dye) contained within the elastomeric envelope capable of leaking out of the envelope and causing a body change detectable to the patient.

See column 5, lines 36-41, teaching adding a pigment/dyes to the provide a colored gel.

Claims 1, 7-10, 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox (4,969,899).

Cox teaches a prosthesis for implant in a human patient body comprising:

at least one elastomeric envelope 41 [and] a filling material 14 contained in the elastomeric envelope; and

a biologically compatible rupture indicator 40 (gel) contained within the elastomeric envelope capable of leaking out of the envelope and causing a body change detectable to the patient.

See valve including elements 30.

Other limitations are self-evident.

Claims 1, 7-8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerow et al (4,795,463).

Gerow teaches a method of detecting rupture of a prosthesis comprising:

(a) implanting a prosthesis containing a fill (chemical indicator), Gerow teaches, "*radiopaque marker which absorbs electromagnetic energy different from the envelop and its contents (chemical indicator) and different from the surrounding breast tissue and in a pattern or configuration which enable roentgenographic determination of whether the envelope is intact, has ruptured.*"

(b) detecting a change locally around the prosthesis using x-ray for indication of leaking out of said indicator from said prosthesis. Note

Additional interpretation of Gerow.

Any material added into the envelope other than the filling material is capable of leaking out and causing at least a change in shape of the implant, illness, etc. which the patient

could detect. Note Gerow teaches the filling materials can be a combination of silica gel and saline, 6:63 et seq. The Examiner interprets the saline as the fill and the silica gel as the rupture indicator.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7-11, 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (4,969,899) in view of Gerow (4,795,463).

Cox teaches a prosthesis comprising:

(a) an external envelope 41 of medical grade elastomer containing a silicone gel fluid material 40 and

(b) an internal envelope 11 of medical grade elastomer disposed within said external envelope, said internal envelope containing an implant filling material. However, Cox is silent regarding a chemical indicator for indicating rupture within the external envelope.

Gerow teaches using radiopaque materials on the envelopes and further teaches it is possible to use a radiopaque material in the silicone gel fill material. See column 5, lines 3-10. It would have been obvious to one having ordinary skill in the art to have utilized the teachings of Gerow and used a radiopaque material in the fill material 14

and 40 to better differentiate from the body or used in combination with radiopaque material on the envelope to check for ruptures of the envelope.

See valves including element 30.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW
PRIMARY EXAMINER